REMARKS

Claims 1-22 are pending in the application.

Claims 9-10 are canceled by the instant amendment.

Claims 8 and 22 have been amended to correct the improper dependency noted by the Examiner in the outstanding office action. Specifically, claim 8 has been amended to incorporate the subject matter of claim 1, and to depend solely from claim 7. Similarly, claim 22 has been amended to incorporate the subject matter of claim 2, and to depend solely from claim 7.

No new matter has been added. Entry of the amendment is respectfully requested.

I. Claims Objections

At paragraph 4 of the Office Action dated June 17, 2002, claims 8 and 22 are objected to under 37 C.F.R. §1.75(c) as being in improper form. The Examiner states that claim 8 should depend from claim 1 or claim 7, but not from both. A similar objection is made to claim 22.

In response, Applicants include herewith amendments to claims 8 and 22. Claim 8 has been amended to incorporate the subject matter of claim 1, and to depend solely from claim 7. Similarly, claim 22 has been amended to incorporate the subject matter of claim 2, and to depend solely from claim 7.

In view of the amendments to the claims, Applicants respectfully request reconsideration and withdrawal of this objection.

II. Rejection of Claims Under 35 U.S.C. §§101 and 112

A. At paragraph 3 of the Office Action dated June 17, 2002, claims 1-8 remain rejected and new claims 11-22 are rejected under 35 U.S.C. §101 as lacking a patentable utility.

The Examiner states that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons of record in the previous Office Action (dated September 24, 2001) at pages 3-6.

In response to Applicants' arguments in the Amendment dated March 25, 2002, the Examiner states in the Office Action dated June 17, 2002, that Applicants have provided convincing evidence that the polypeptides of the present invention are members of the TNFR family.

The Examiner goes on to discuss the Eby et al. reference and states that the TAJ protein disclosed therein is a likely splice variant of SEQ ID NO: 4 of the present invention. Indeed, the Examiner recognizes that TAJ is equivalent to SEQ ID NO:4 of the present invention (encoding OAF065α) at page 5, lines 3-4, of the office action.

The Examiner further states that while Eby et al. suggests a role for the proteins in TRAF-mediated signal transduction pathways and apoptosis, such functions are not present or envisioned in the specification as originally filed.

In response, Applicants filed an Amendment dated December 17, 2002, and asserted therein that as both the TAJ protein and the protein of the present invention are substantially the same, the protein of the present application has the same function and activity as the TAJ protein, namely, the ability to induce cell death. Applicants also discussed support in the specification for the cell death inducing activity of the present invention. Applicants incorporate herein by reference their statements made in the Amendment dated December 17, 2002.

In the Advisory Action dated January 17, 2003, responsive to the Amendment dated December 17, 2002, the Examiner states that Applicants' arguments are not persuasive because

while Eby et al. supports the assertion that the proteins of the instant invention are somehow involved in cell death, it is very specific and also differs in mechanism from other TNF receptors. The Examiner also states that Eby et al. presents evidence that the TAJ protein is expressed specifically in the prostate gland, with very low expression in other tissues, which was not disclosed in the specification, and that Eby et al. demonstrates that the apoptotic mechanism is different from that of other TNF receptor family members and induces death in some cells but not others. The Examiner concludes that at the time of filing, the specification did not support a utility for the proteins or nucleic acids of the instant application.

Applicants' comments

As discussed in the Amendment filed December 17, 2002, the TAJ protein of Eby et al. and the protein of the present invention are substantially the same. Thus, the protein of the present invention would be readily expected to have the same activity as established for the TAJ protein, namely, the ability to induce cell death.

The present specification discloses and supports as one of the activities of the protein of the invention the ability to induce cell death. For example, at page 17, lines 6-10, it is stated that the polypeptide of the present invention will show biological activities including cell death. This activity is supported in the disclosure of Eby et al., such as in the Abstract.

While the Examiner states that the TAJ protein has specific tissue expression, and such expression is not supported by the specification of the instant application, Applicants respectfully disagree. As discussed throughout Eby et al., the primary activity for the TAJ protein is predicted to be in embryonic development (*see, e.g.*, the Abstract; page 15336, column 2, lines 3-6; page 15340, column 2, lines 5-7). This activity is fully supported in the specification, such as

at page 18, lines 4-7, where cell proliferation and differentiation activities are discussed; at page 19, line 25 through page 20, line 1, where growth and proliferation of erythroid progenitor cells are discussed; page 20, line 6, where growth and proliferation of myeloid cells are discussed; page 20, line 10, where growth and proliferation of megakaryocytes are discussed; page 20, lines 15-16, where growth and proliferation of hematopoietic stem cells are discussed. Finally, as clearly stated at page 29, lines 13-21, the protein of the present invention is involved in the early embryonic development of an organism.

While it is disclosed in Eby et al. that the TAJ protein is expressed in the prostate gland, a role for the protein in this gland is not discussed or predicted in the publication.

Based on the disclosed activities of the present invention, supported by Eby et al., the skilled artisan would readily understand that a polypeptide involved in the induction of cell death could be used in a number of important manners. For example, a specific and substantial utility could be had in the preparation of an agent for treating or diagnosing diseases caused by uncontrolled cell death induced by the aberrant expression of the protein of the present invention. A discussion of some of the other specific utilities for the polypeptide of the present invention is provided at page 29, line 22, through page 30, line 8.

In conclusion, Applicants assert that the protein of the present invention would be expected to have cell death promoting activity, based on its sequence homology to the TAJ protein of Eby et al. Furthermore, as discussed above, a role for the TAJ protein in embryonic development has been disclosed in Eby et al., which is fully supported in the instant specification where numerous instances of a role for the protein in cellular proliferation and differentiation are

discussed. Finally, as also disclosed in the specification, a number of specific utilities for the protein are taught, and the skilled artisan would readily envision additional activities.

Thus, it is clear that a specific and substantial asserted utility has been disclosed for the polypeptide of the present invention, and that the experimental results in Eby et al. strongly support that utility.

In view of the points discussed above, and the evidence for a specific and substantial asserted utility for the polypeptide of the present invention, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 4 of the Office Action, claims 1-8 remain rejected and new claims 11-22 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner asserts that because the claimed invention is allegedly not supported by either a specific and substantial asserted utility, or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicants' comments

In response, Applicants again assert that the claimed invention is supported by a specific and substantial asserted utility for the reasons discussed above.

Furthermore, the skilled artisan would clearly understand how to make and use the polypeptide of the present invention for the asserted utility without undue experimentation. The knowledge in the art and the expertise of an artisan working in the field of molecular biology is such that the skilled artisan would be able to use the claimed polypeptide for those uses discussed at page 29, line 22, through page 30, line 8, of the specification, without further specific instruction. One example would be in the induction of cell death in a population of

cancer cells through the introduction into the population of an expression vector comprising the coding sequence of the polypeptide.

Given the specific and substantial asserted utility, and the knowledge of the skilled artisan, Applicants state that the present invention is adequately enabled and therefore respectfully request reconsideration and withdrawal of this rejection.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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